SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

OSTEORAPTOR™ OS Suture Anchor

Date Prepared: 10 November 2010

JAN 27 2011

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Julie Acker, RAC

Senior Regulatory Affairs Specialist

Phone: (508) 261-3618

Fax: (508) 261-3620

C. Device Name

Trade Name:	OSTEORAPTOR OS Suture Anchor
Common Name:	Suture Anchor
Classification Name:	Fastener, Fixation, Biodegradable, Soft Tissue
Product Code	MAI
Regulation Number:	21 CFR § 888.3030

D. Predicate Devices

The Smith & Nephew Osteoraptor OS Suture Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: Smith & Nephew OSTEORAPTOR Suture Anchors (K082215) and DePuy Mitek LUPINE BR Anchor (K070925).

E. Description of Device

The Smith & Nephew OSTEORAPTOR OS Suture Anchor is a fixation device intended to provide secure attachment of soft tissue to bone until healing occurs. The device consists of a resorbable composite suture anchor with attached non-absorbable suture(s) preloaded onto an insertion device. A 24 month ovine bone implantation study demonstrated that 9x10 mm

implants typically resorb in approximately two years and are replaced by bone. This device is provided sterile, for single use only.

Intended Use
The Smith & Nephew Osteoraptor OS Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament. reconstructions
Lateral epicondylitis repair

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

Hip
Hip capsule repair

- Acetabular labrum reattachment

Knee
Extra-capsular repairs:
– Medial collateral ligament

– Lateral collateral ligament
– Posterior oblique ligament
Patellar realignment and tendon repairs
– Vastus medialis obliquous advancement
Iliotibial band tenodesis

Shoulder
Capsular stabilization

- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

F. Comparison of Technological Characteristics

The intended use; operating principle and design features of the Osteoraptor OS Suture Anchors are substantially equivalent to the legally marketed predicate anchors. Osteoraptor OS anchors are identical in design and intended use to the predicate Osteoraptor anchors except for the anchor material.

G. Summary Performance Data

Results of biocompatibility studies, animal studies, and in vitro testing demonstrate that Osteoraptor OS Anchors are substantially equivalent to predicate devices and the proposed modification to the anchor material does not raise new questions of safety and efficacy for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 27 2011

Smith & Nephew, Inc.
Endoscopy Division
% Julie Acker
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

Re: K101459
Trade/Device Name: OSTEORAPTOR OS Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: January 26, 2011
Received: January 27, 2011

Dear Ms. Acker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101459 (pg 1/1)

Device Name: Osteoraptor II Suture Anchors

The Smith & Nephew Osteoraptor II Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

Hip
Hip capsule repair
- Acetabular labrum reattachment

Knee
Extra-capsular repairs:
– Medial collateral ligament
– Lateral collateral ligament
– Posterior oblique ligament
Patellar realignment and tendon repairs
– Vastus medialis obliquous advancement
Iliotibial band tenodesis

Shoulder
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions
Acromioclavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. McKenna

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101459